

(NPIP staff) every 3 years. The Service's review may include, but will not necessarily be limited to, checking records, laboratory protocol, check-test proficiency, technician training, and peer review.

(f) *Reporting.* (1) A memorandum of understanding or other means shall be used to establish testing and reporting criteria to the Official State Agency, including criteria that provide for reporting H5 and H7 low pathogenic avian influenza directly to the Service.

(2) *Salmonella pullorum* and *Mycoplasma* Plan disease reactors must be reported to the Official State Agency within 48 hours.

(g) *Verification.* Random samples may also be required to be submitted for verification as specified by the Official State Agency.

§ 147.52 Approved tests.

(a) The procedures for the bacteriological examination of poultry and poultry environments described in this part are approved tests for use in the NPIP. In addition, all tests that use veterinary biologics (e.g., antiserum and other products of biological origin) that are licensed or produced by the Service and used as described in this part are approved for use in the NPIP.

(b) Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) may be approved through the following procedure:

(1) The sensitivity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known positive samples, as determined by the official NPIP procedures found in Subparts A, B, C, and D of this part. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(2) The specificity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known negative samples, as determined by the official NPIP procedures found in this part. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and sig-

nificance of the effect(s) can be evaluated.

(3) The kit will be provided to the cooperating laboratories in its final form and include the instructions for use. The cooperating laboratories must perform the assay exactly as stated in the supplied instructions. Each laboratory must test a panel of at least 25 known positive clinical samples supplied by the manufacturer of the test kit. In addition, each laboratory will be asked to test 50 known negative clinical samples obtained from several sources, to provide a representative sampling of the general population. The identity of the samples must be coded so that the cooperating laboratories are blinded to identity and classification. Each sample must be provided in duplicate or triplicate, so that error and repeatability data may be generated.

(4) Cooperating laboratories will submit to the kit manufacturer all raw data regarding the assay response. Each sample tested will be reported as positive or negative, and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value.

(5) The findings of the cooperating laboratories will be evaluated by the NPIP technical committee, and the technical committee will make a recommendation regarding whether to approve the test kit to the General Conference Committee. If the technical committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46 and 147.47.

(c) The following diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) are approved for use in the NPIP:

(1) Rapid Chek[®]; Select TMSalmonella Test Kit, Strategic Diagnostics, Inc., Newark, DE 19713.

(2) ADIAFOOD Rapid Pathogen Detection System for *Salmonella* spp., AES Chemunex Canada. Laval, QC (Canada) H7L4S3.

(3) DuPont Qualicon BAX Polymerase Chain Reaction (PCR)-based assay for *Salmonella*, DuPont Qualicon, Wilmington, DE 19810.

[74 FR 14718, Apr. 1, 2009, as amended at 76 FR 15798, Mar. 22, 2011]

PART 149—VOLUNTARY TRICHINAE CERTIFICATION PROGRAM

Sec.

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AUTHORITY: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136a; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 73 FR 60479, Oct. 10, 2008, unless otherwise noted.

§ 149.0 Purpose and scope.

The Trichinae Certification Program described in this part is intended to enhance the ability of swine producers, as well as slaughter facilities and other persons that handle or process swine from pork production sites that have been certified under the program, to export fresh pork and pork products to foreign markets.

§ 149.1 Definitions.

Accredited veterinarian. A veterinarian approved by the APHIS Administrator in accordance with part 161 of this chapter to perform functions specified in subchapters B, C, D, and G of this chapter.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

AMS Administrator. The Administrator, Agricultural Marketing Service, or any person authorized to act for the AMS Administrator.

AMS representative. Any individual employed by or acting as an agent on behalf of the Agricultural Marketing Service who is authorized by the AMS Administrator to perform services required by this part.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Animal disposal plan. A written document that describes methods for the removal and disposal of dead swine or

swine remains from a pork production site.

Animal movement record. A written record of the movement of swine into or from a pork production site.

APHIS Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the APHIS Administrator.

APHIS representative. Any individual employed by or acting as an agent on behalf of the Animal and Plant Health Inspection Service who is authorized by the APHIS Administrator to perform the services required by this part.

Approved laboratory. A non-Federal laboratory approved by the Agricultural Marketing Service and recognized by the APHIS Administrator or FSIS Administrator for performing validated tests to determine the presence of trichinae infection in reference to the Trichinae Certification Program.

Audit. An inspection process, as provided in this part, that generates a written record documenting a pork production site's adherence to the required good production practices.

Auditor. A qualified accredited veterinarian (QAV) or a qualified veterinary medical officer (QVMO) who is trained and authorized by APHIS to perform auditing activities under the Trichinae Certification Program.

Certification (certified). A designation given by the APHIS Administrator to a pork production site for compliance with good production practices and other program requirements of the Trichinae Certification Program as provided in this part.

Certified pork. Pork products originating from certified swine from a certified production site with identity of such animals or carcasses maintained throughout receiving, handling, and processing.¹

Certified production site. A pork production site that has attained a program status of Stage II or higher, based on adherence to good production practices and other program requirements as provided in this part.

¹The labeling of all certified pork or pork products leaving a slaughter or processing facility must comply with 9 CFR 317.4 and all other applicable FSIS labeling regulations.